



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,161	03/19/2004	Junichi Iwata	8050-1007-1	7412
466	7590	10/20/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			PENG, KUO LIANG	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,161

Applicant(s)

IWATA ET AL.

Examiner

Kuo-Liang Peng

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/26/05 Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' amendment filed on July 16, 2005 was received. Claim 3 is deleted. Claims 1-2 and 4-6 are amended. Claims 7-19 are added.

2. Newly submitted Claims 15-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly added Claims 15-18 are directed to a hydrophilic polysiloxane monomer, while the originally present invention is directed to a mold. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 15-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Now, Claims 1-2, 4-14 and 19 are pending for consideration.

3. The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action (Paper No. 0105).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 4, 7-10 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 8, 48, 59-60 and 64-65 of U.S. Patent No. 6 867 245. Although the conflicting claims are not identical, they are not patentable distinct from each other because of the following reason: Claims 8, 48, 59-60 and 64-65 of US 6 867 245 being directed to a contact lens and a method of making a contact lens utilizing a specific type of mold, which obviously reads on the embodiments of Claims 4, 7-10 and 13-14 of the present invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-11 and 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-8 recite the limitation "said mold" in Claim 7 (lines 2-3). There is insufficient antecedent basis for this limitation in the claim.

Claims 9-10 recite the limitation "said mold" in Claim 9 (line 3). There is insufficient antecedent basis for this limitation in the claim.

In Claim 11 (line 2), it is not clear as to what extent of "enhanced" refers to.

In Claim 19 (last line), it is not clear as to how the contact angle is determined.

Claim Rejections - 35 USC § 102

8. Claims 2, 7-10 and 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Onozuka (JP 02-503028) as evidenced by Oertel (US 4 153 596).

The following page and paragraph numbers of Onozuka are based on Derwent Machine-Assisted Translation.

For Claim 2, the instant claim is directed to a mold. Therefore, “for producing a contact lens” and the specific materials and final properties of the contact lenses do not carry any weight of patentability. In other words, “for producing a contact lens” and the specific materials and final properties of the contact lenses are merely the intended use of the mold for, the intended material to be used or the intended properties of the contact lenses to obtain. As such, they do not carry any weight of patentability. Onozuka discloses a mold made of ethylene-vinylalcohol copolymer. Note that Onozuka further teaches the use of GL resin (Nippon Synthetic Chemical Industry Co., Ltd.)(Examples) Oertel teaches that this resin is an almost completely hydrolyzed ethylene-vinylacetate copolymer containing about 85 wt% of vinylacetate before hydrolysis. (Example 22) Therefore, this resin contains about 35 mol% of ethylene. Even if the aforementioned intended use of the mold is considered for having weight of patentability, Onozuka teaches the use of the mold for producing a contact lens.

For Claims 7-10, Onozuka further teaches the use of a siloxane monomer. (page 11, last paragraph) For Claim 19, since Onozuka’s mold reads on

Art Unit: 1712

Applicants' mold, they should possess the same properties, e.g., water contact angle, etc. *In re Best*, 195 USPQ 430 (CCPA 1977).

9. Claims 7-10, 13-14 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shepherd (US 4 121 896).

Shepherd discloses a contact lens mold that comprises a male portion and a female portion (col. 2, lines 6-17, Examples 1(b) and 3(b)). Shepherd further especially suitable mold materials include ethylene vinyl alcohol copolymers, Nylon 6, Nylon 66, thermoplastic polyesters, etc. (col. 5, lines 15-33). Note that for lens material, a monomer mixture comprising a siloxane monomer and a hydrophilic monomer can be used. These monomers can be photopolymerized. (col. 7, lines 49 to col. 8, line 5) Since Shepherd's mold reads on Applicants' mold, they should possess the same properties, e.g., water contact angle, etc. *In re Best*, 195 USPQ 430 (CCPA 1977).

10. Claims 7-10, 13-14 and 19 are rejected under 35 U.S.C. 102(a),(e) as being anticipated by Oyama (US 6 158 861).

Oyama discloses a contact lens mold that comprises a male portion and a female portion. Oyama further especially suitable mold materials include ethylene

Art Unit: 1712

vinyl alcohol copolymers, polyamide, polyesters, etc. (col. 5, line 44 to col. 7, line 7). Note that for lens material, a monomer mixture comprising a siloxane monomer and a hydrophilic monomer can be used. These monomers can be photopolymerized. (col. 4, lines 11-19 and col. 7, lines 8-33) Since Oyama's mold reads on Applicants' mold, they should possess the same properties, e.g., water contact angle, etc. *In re Best*, 195 USPQ 430 (CCPA 1977).

11. Claims 7-10 and 19 are rejected under 35 U.S.C. 102(a),(e) as being anticipated by LeFevre (US 4 208 365) as evidenced by Wajs (US 4 062 627).

LeFevre discloses a contact lens mold that comprises a male portion and a female portion. LeFevre further especially suitable mold materials include ethylene vinyl alcohol copolymers, Nylon 6, Nylon 66, thermoplastic polyesters, etc. (col. 2, lines 18-53 and col. 5, line 63 to col. 6, line 62). LeFevre further teaches the use of lens material taught in Wajs. Thus, Wajs teaches a lens derived from a siloxane monomer and hydrophilic monomer. (col. 2, line 63 to col. 4, line 43 and Examples) Since LeFevre's mold reads on Applicants' mold, they should possess the same properties, e.g., water contact angle, etc. *In re Best*, 195 USPQ 430 (CCPA 1977). Applicants argue that LeFevre uses a polypropylene mold in Examples. However, note that using a polypropylene mold is merely a preferred

Art Unit: 1712

embodiment. LeFevre certainly does not teach away the use of other disclosed molds.

12. Claims 7-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP857 (JP 06-170857)

JP857 discloses a contact lens mold that comprises a male portion and a female portion. JP857 further especially suitable mold materials include ethylene vinyl alcohol copolymers, polyamides, etc. ([0017]-[0031]). Note that for lens material, a monomer mixture comprising a siloxane monomer and a hydrophilic monomer such as (meth)acrylic acid, etc. can be used. ([0037]) Applicants argue that JP857's female mold material is different from the male mold material. However, note that the word "comprising" in the instant claims does not exclude a) the mold material containing other materials than the ones claimed, or b) the materials for male mold and female mold being different. Furthermore, the instant claims do not exclude the possibility of any post-molding treatment of the lens, such as lathing, etc. Furthermore, JP857 does also teach the use of the same material for both male mold and female mold. ([0033])

Art Unit: 1712

13. Claims 2, 7-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP378 (JP 08-025378).

JP378 discloses a contact lens mold that comprises a male portion and a female portion. JP378 further teaches that especially suitable mold materials include ethylene vinyl alcohol copolymers, polyamides, polyesters, etc. (Claims). Soarlite (a ethylene vinylalcohol copolymer) is used for making the male mold. (Examples) Note that Applicants admit in the specification (page 55, line 21 to page 56, line 10) that Soarlite has an ethylene content which reads on the ethylene content of the ethylene vinylalcohol copolymer set forth in Claim 2. These monomers can be photopolymerized. (Examples) Note that for lens material, a monomer mixture comprising a siloxane monomer and a hydrophilic monomer such as (meth)acrylic acid, etc. can be used. ([0033]) Applicants argue that JP378's female mold material is different from the male mold material. However, note that the word "comprising" in the instant claims does not exclude a) the mold material containing other materials than the ones claimed, or b) the materials for male mold and female mold being different. Furthermore, the instant claims do not exclude the possibility of any post-molding treatment of the lens, such as lathing, etc.

14. Claims 7-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by JP699 (JP 11-320699).

JP699 discloses a mold that comprises a male portion and a female portion. JP699 further especially suitable mold materials include ethylene vinyl alcohol copolymers, polyamides, polyesters, etc. ([0019]-[0024]). Note that for lens material, a monomer mixture comprising a siloxane monomer and a hydrophilic monomer such as (meth)acrylic acid, etc. can be used. ([0025]) Applicants argue that JP699's female mold material is different from the male mold material. However, note that the word "comprising" in the instant claims does not exclude a) the mold material containing other materials than the ones claimed, or b) the materials for male mold and female mold being different. Furthermore, the instant claims do not exclude the possibility of any post-molding treatment of the lens, such as lathing, etc.

15. Claims 1, 4, 7, 9, 13 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hwang (US 4 786 444).

Hwang discloses a contact lens mold made of poly(ethylene terephthalate). The mold can be used for preparing a hydrogel soft contact lens derived from a siloxane monomer via photopolymerization. (col. 1, line 50 to col. 2, line 29, col.

Art Unit: 1712

6, lines 18-50 and Examples) Since Hwang's mold reads on Applicants' mold, they should possess the same properties, e.g., water contact angle, etc. *In re Best*, 195 USPQ 430 (CCPA 1977).

16. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by JP737 (JP 08-245737)

JP737 discloses a hydrogel soft contact lens derived from a hydrophilic polysiloxane monomer and a hydrophilic monomer such as acrylic acid, etc. ([0007]-[0013] and [0022]). It is noted that JP737 is silent on the use of the specific mold material set forth in the instant claims. However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onozuka as evidenced by Oertel further in view of Futamura (US 5 264 465).

The following page and paragraph numbers of Onozuka are based on Derwent Machine-Assisted Translation.

Onozuka teaches the use of the mold for producing a contact lens, supra, which is incorporated herein by reference. Onozuka further discloses a method for preparing the contact lens by radical polymerizing (meth)acryl containing monomers such as siloxane monomers, etc. at an elevated temperature using peroxides or azo initiators. (page 11, last paragraph and page 12, 2nd and 3rd paragraphs) Futamura teaches a method of making contact lenses by radical polymerizing (meth)acryl containing monomers such as siloxane monomers, etc. using thermal initiators such as peroxides and azo initiators or photoinitiators such

Art Unit: 1712

as benzoin methyl ether, etc. (col. 7, lines 4-23 and col. 8, lines 5-54) As such, Futamura teaches the equivalency and exchangeability of thermal polymerization and photo-polymerization in terms of polymerization. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize Futamura's photopolymerization technique for polymerizing Onozuka's monomers with expected success. See MPEP 2144.06

12. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang in view of JP737.

Hwang discloses a contact lens prepared by polymerizing a siloxane monomer in a polyethylene terephthalate mold, supra, which is incorporated herein by reference. Hwang is silent on the specific use of the hydrophilic polysiloxane monomer set forth in the instant claim. However, JP737 teaches the use of a hydrophilic polysiloxane monomer for preparing a contact lens. The motivation of using such a hydrophilic polysiloxane monomer is to afford a contact lens having excellent flexibility, strength, optical clarity, hydrophilicity, soiling resistance, protein deposition resistance, etc. ([0005]-[0006]) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize JP737's hydrophilic polysiloxane monomer in Hwang's mold for making

Art Unit: 1712

contact lenses. JP737 further teaches the use of hydrophilic monomer such as acrylic acid, etc. ([0022])

13. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang in view of Mark (Encyclopedia of Polymer Science and Engineering, (1988), vol. 12, pages 193-200, 217 and 225-229).

Hwang discloses a polyethylene terephthalate mold for making contact lens, supra, which is incorporated herein by reference. Hwang is silent on the use of the specific mold set forth in the instant claims. However, it is noted that the physical strength and dimensional stability of a mold is very critical in order to manufacture optical precision articles such as contact lenses. Furthermore, Mark teaches for a polyester material, such as polyethylene terephthalate, that “linear coefficient of thermal expansion decreases with increasing draw ratio” (page 198, last paragraph), “crystallinity and strength can be enhanced through mechanical orientation, e.g., ... biaxially oriented films...” (page 227, 2nd paragraph from bottom) and “high rates of crystallization [to reach a desired degree of crystallinity] ensure short processing cycles and excellent thermodynamically and dimensionally stable parts” (page 22, last paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize a

Art Unit: 1712

polyethylene terephthalate mold with enhanced crystallinity via orientating the material such as drawing.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is

Art Unit: 1712

(571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp
October 14, 2005


Kuo-Liang Peng
Primary Examiner
Art Unit 1712